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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,288	02/06/2006	Mark J. Redmond	2315-127	3148

6449 7590 01/24/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,288	REDMOND ET AL.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-16 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-16 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment was received and entered on October 25, 2007. All evidence and arguments have been fully considered. Claims 12, 13 and 17-27 are cancelled. Claims 1-11, 14-16 and 28-31 are pending and examined on the merits in this office action.

Response to Amendment

The amendment to the claims filed on October 25, 2007 does not comply with the requirements of 37 CFR 1.121(c) because the amendment to claim 16 uses improper marking to add and delete subject matter. The changes to step (ii) of the claim to further limit the coagulants and flocculants used in the method should have been indicated by underlining added text and using double-brackets or strike-through to indicate deleted text as set forth below. Since the response appears to be *bona fide*, the amendment has been entered.

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

> (c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. **The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.** Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Specification

1. The objections to the specification have been withdrawn due to amendment

Claim Objections

2. Claim objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

3. Rejections under 35 USC 102 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6, 9, 11, 14, 15 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatty (US 5,518,710) in view of Potter et al. (US 6,323,338). Claim 1 recites a method of isolating beta (1-3) beta (1-4) glucan (referred to as beta glucan in this office action) from milled cereal grain or a milled part of the cereal grain comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from between 10% to 20% (vol/vol) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 2 and 3 further limit claim 1 by reciting the limitation that the C_1-C_4 alcohol is selected from the group consisting of methanol, ethanol and isopropanol, specifically ethanol. Claim 4 further limits claim 1 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 5 further limits claim 4

by reciting the limitation that the starch material is digested with an enzyme. Claim 6 further limits claim 5 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claim 9 further limits claim 5 by reciting the limitation that the enzyme is an amylase. Claim 11 further limits claim 1 by reciting that the cereal is selected fro the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, and a cultivar of corn. Claim 14 further limits claim 1 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 15 further limits claim 1 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding between 10% to 20% (vol/vol) of the C_1-C_4 alcohol to the aqueous solution, and isolating the beta glucan. Claim 29 recites the method of claim 1 wherein about 15% to about 17% (vol/vol) of the C_1-C_4 alcohol is added to the purified extract in step (iii). Claims 30 and 31 recite the method of claim 16 wherein about 10 to about 20% (vol/vol), specifically about 15% to about 17% (vol/vol), of the C_1-C_4 alcohol is added to the purified extract in step (iii).

8. Bhatty teaches a method for extracting beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) from milled cereal grain (including cultivars of barley, oat, wheat, rye, corn, sorghum and millet; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14, particularly pH 10-12 (col. 3, lines 22-27), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatty would inherently be larger than 0.2 microns;

col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C_1 to C_4 alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by the methods claimed in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches that the pH of the alkaline solution can adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to

the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). The alkaline extraction step of Bhatty is generally carried out for between about 2 and about 25 hours (col. 3, lines 41-42). The reference does not teach that the step of extracting the beta glucan with alkaline solution is carried out for about 15 to about 45 minutes.

9. Potter teaches a method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours (abstract, col. 5, lines 13-18).

10. A method for the extraction of beta glucan using the claimed reaction conditions was known in the art at the time of the invention, as taught by Bhatty and discussed above. A method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours was also known in the art at the time of the invention, as taught by Potter One would be motivated to combine the teachings of Bhatty and Potter because Potter discusses the need for efficient processes for extraction of beta glucan (col. 2, lines 23-27) and Bhatty teaches that the extraction time can vary (col. 3, lines 41-45). One skilled in the art would therefore have been motivated to reduce the time of the alkaline extraction step of the method for extraction of beta glucan taught by Bhatty to about 0.5 to about 3 hours, as taught by Potter in the course of routine experimentation. Further, although applicant recites in some of the dependent claims the use of up to about 17% alcohol to precipitate the purified extract,

Bhatty teaches the use of "about 20%" alcohol to precipitate the purified extract; even if it is found that "about 20%" alcohol does not anticipate applicant's recitation of "about 17%" alcohol, this amount have been arrived at by one of ordinary skill in the art in the course of routine experimentation, as evidenced by Bhatty's teaching that the amount of alcohol used to precipitate the purified extract can be varied (col. 4, lines 1-8). One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of Bhatty and Potter to develop a method for extraction of beta glucan using the claimed conditions with a shorter length of time for the alkaline extraction step because it was known in the art at the time of the invention that beta glucans could be extracted from milled cereal grain using an alkaline extraction step that is carried out for about 0.5 to about 3 hours, as taught by Potter. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at a method for extraction of beta glucan using the claimed conditions.

11. Claim 1-9, 11, 14, 15 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatty (US 5,518,710) in view of Potter et al. (US 6,323,338) as applied to claims 1-6, 9, 11, 14, 15 and 29-31 above, and further in view of Puski et al. (US 4,830,861).

12. Claim 1 recites a method of isolating beta (1-3) beta (1-4) glucan (referred to as beta glucan in this office action) from milled cereal grain or a milled part of the cereal grain comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a pH of between 9 to 10 for a period of time of

about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from between 10% to 20% (vol/vol) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 2 and 3 further limit claim 1 by reciting the limitation that the C_1-C_4 alcohol is selected from the group consisting of methanol, ethanol and isopropanol, specifically ethanol. Claim 4 further limits claim 1 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 5 further limits claim 4 by reciting the limitation that the starch material is digested with an enzyme. Claim 6 further limits claim 5 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claims 7 and 8 recite the method claim 6 wherein, following the digestion of the starch material, the enzyme is inactivated, specifically by acidifying the neutralized solution. Claim 9 further limits claim 5 by reciting the limitation that the enzyme is an amylase. Claim 11 further limits claim 1 by reciting that the cereal is selected fro the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, and a cultivar of corn. Claim 14 further limits claim 1 by reciting the

limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 15 further limits claim 1 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding between 10% to 20% (vol/vol) of the C_1-C_4 alcohol to the aqueous solution, and isolating the beta glucan. Claim 29 recites the method of claim 1 wherein about 15% to about 17% (vol/vol) of the C_1-C_4 alcohol is added to the purified extract in step (iii). Claims 30 and 31 recite the method of claim 16 wherein about 10 to about 20% (vol/vol), specifically about 15% to about 17% (vol/vol), of the C_1-C_4 alcohol is added to the purified extract in step (iii).

13. Bhatty teaches a method for extracting beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) from milled cereal grain (including cultivars of barley, oat, wheat, rye, corn, sorghum and millet; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14, particularly pH 10-12 (col. 3, lines 22-27), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatty would inherently be larger than 0.2 microns; col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C_1 to C_4 alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials

contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by the methods claimed in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches that the pH of the alkaline solution can adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). The alkaline extraction step of Bhatty is generally carried out for between about 2 and about 25 hours (col. 3, lines 41-42).

14. Potter teaches a method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours (abstract, col. 5, lines 13-18).

15. As discussed above, it would have been obvious to combine the teachings of Bhatty and Potter to arrive at a method for the extraction of beta glucan comprising nearly all of the claimed elements. Neither of the references, however, teaches the inactivation of the enzyme, particularly inactivation using an acid.

16. Puski teaches the use of amylase for digestion of starch and inactivation of the enzyme using an acid (col. 16, lines 55-63).

17. As discussed above, a process for extraction of beta glucan from milled cereal grain comprising the nearly all of the claimed steps was known at the time of the invention, as taught by Bhatty and Potter. It was also known in the art at the time of the invention that an enzyme (amylase) could be inactivated in a reaction mixture by acidifying the solution, as taught by Puski The motivation to combine the teachings of Bhatty and Puski is taught by Puski, who teaches that the inactivation of amylase in a reaction mixture is desirable (col. 1, lines 55-63). One of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings discussed above by denaturing the enzyme in the reaction mixture for the extraction of beta glucan from milled cereal grain because Bhatty teaches that the reaction mixture could be acidified to a pH as low as 2 (col. 3, lines 48-52). Puski teaches that the use of a pH of 3.8 is sufficient to inactivate the amylase in the reaction mixture (col. 16, lines 61-62). It would therefore have been obvious to one of ordinary skill in the art at the time of the

invention to combine the teachings discussed above to develop the claimed method for extraction of beta glucan.

18. Claim 1-6, 9-11, 14, 15 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatty (US 5,518,710) in view of Potter et al. (US 6,323,338) as applied to claims 1-6, 9, 11, 14, 15 and 29-31 above, and further in view of Novozymes (June 1, 2002, novozymes.com). Claim 1 recites a method of isolating beta (1-3) beta (1-4) glucan (referred to as beta glucan in this office action) from milled cereal grain or a milled part of the cereal grain comprising: (i) extracting the milled cereal grain or the milled part of the cereal grain with an alkaline solution having a pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from between 10% to 20% (vol/vol) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 2 and 3 further limit claim 1 by reciting the limitation that the C_1-C_4 alcohol is selected from the group consisting of methanol, ethanol and isopropanol, specifically ethanol. Claim 4 further limits claim 1 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material

having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 5 further limits claim 4 by reciting the limitation that the starch material is digested with an enzyme. Claim 6 further limits claim 5 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claim 9 further limits claim 5 by reciting the limitation that the enzyme is an amylase. Claim 10 recites the method of claim 9, wherein the amylase does not require a calcium cofactor. Claim 11 further limits claim 1 by reciting that the cereal is selected fro the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, and a cultivar of corn. Claim 14 further limits claim 1 by reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 15 further limits claim 1 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding between 10% to 20% (vol/vol) of the C_1-C_4 alcohol to the aqueous solution, and isolating the beta glucan. Claim 29 recites the method of claim 1 wherein about 15% to about 17% (vol/vol) of the C_1-C_4 alcohol is added to the purified extract in step (iii). Claims 30 and 31 recite the method of claim 16 wherein about 10 to about 20% (vol/vol), specifically about 15% to about 17% (vol/vol), of the C_1-C_4 alcohol is added to the purified extract in step (iii).

19. Bhatty teaches a method for extracting beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) from milled cereal grain (including cultivars of barley, oat, wheat, rye, corn, sorghum and millet; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14, particularly pH 10-12 (col. 3,

lines 22-27), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatty would inherently be larger than 0.2 microns; col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C_1 to C_4 alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3% beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by the methods claimed in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches

that the pH of the alkaline solution can adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). The alkaline extraction step of Bhatty is generally carried out for between about 2 and about 25 hours (col. 3, lines 41-42).

20. Potter teaches a method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours (abstract, col. 5, lines 13-18).

21. As discussed above, it would have been obvious to combine the teachings of Bhatty and Potter to arrive at a method for the extraction of beta glucan comprising nearly all of the claimed elements. Neither of the references, however, teaches the use of an amylase that does not require a calcium cofactor.

22. Novozymes teaches an amylase, TERMAMYL ULTRA 300 L, that does not require a calcium cofactor (p. 1, paragraph 6).

23. A method for extraction of beta glucan using the claimed conditions comprising the addition of amylase to the reaction mixture was known in the art at the time of the invention, as discussed above. Further, an amylase that does not require the addition of a calcium cofactor was known in the art at the time of the invention, as taught by Novozymes. One of ordinary skill in the art would have been motivated to combine the teachings of Bhatty and Novozymes because Bhatty discusses the use of TERMAMYL

and the addition of calcium ions for the enhancement of the enzyme (col. 3, lines 60-62). Novozymes discusses an improvement to the TERMAMYL enzyme (TERMAMYL ULTRA 300 L) that makes it more stable in the absence of calcium ions, and that the addition of calcium ions is not always sufficient for maintaining the stability of the enzyme (p. 1, paragraphs 4 and 6). One skilled in the art would therefore have been motivated to use the improved enzyme taught by Novozymes in a method for extraction of beta glucan which uses TERMAMYL. One of ordinary skill in the art would have had a reasonable expectation of success in combining the use of an amylase that does not require the addition of a calcium cofactor with a method for the extraction of beta glucan using the claimed conditions because it was known in the art at the time of the invention that TERMAMYL was a compatible enzyme for use the extraction of beta glucan, as taught by Bhatty, and that the TERMAMYL ULTRA 300 L is an improvement of that enzyme with the same function. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

24. Claim 1-6, 9-11, 14-16 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatty (US 5,518,710) in view of Potter et al. (US 6,323,338) as applied to claims 1-6, 9, 11, 14, 15 and 29-31 above, and further in view of Morgan (WO/2001/057092 A1). Claim 1 recites a method of isolating beta (1-3) beta (1-4) glucan (referred to as beta glucan in this office action) from milled cereal grain or a milled part of the cereal grain comprising: (i) extracting the milled cereal grain or the

milled part of the cereal grain with an alkaline solution having a pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract containing at least about 0.4 weight % beta glucan; (ii) removing insoluble material, and removing particulate material having a particle size of greater than about 0.2 micron from said extract to produce a purified extract; (iii) adding from between 10% to 20% (vol/vol) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claims 2 and 3 further limit claim 1 by reciting the limitation that the C_1-C_4 alcohol is selected from the group consisting of methanol, ethanol and isopropanol, specifically ethanol. Claim 4 further limits claim 1 by reciting the limitation that the step of removing the particulate material comprises adding a flocculant, a coagulant of both a flocculant and a coagulant to the extract to coagulate particulate material having a particle size of greater than 0.2 microns, and removing coagulated material from said extract; digesting starch material in said extract; and filtering out particulate material having a particle size of greater than 0.2 microns from said extract to produce a purified extract. Claim 5 further limits claim 4 by reciting the limitation that the starch material is digested with an enzyme. Claim 6 further limits claim 5 by reciting the limitation that, prior to digestion of starch material, the alkaline solution is neutralized. Claim 9 further limits claim 5 by reciting the limitation that the enzyme is an amylase. Claim 10 recites the method of claim 9, wherein the amylase does not require a calcium cofactor. Claim 11 further limits claim 1 by reciting that the cereal is selected fro the group consisting of a cultivar of barley, a cultivar of oat, a cultivar of wheat, a cultivar of rye, a cultivar of sorghum, a cultivar of millet, and a cultivar of corn. Claim 14 further limits claim 1 by

reciting the limitation that step (iii) conducted at a temperature of from about 1 degree C to about 10 degrees C. Claim 15 further limits claim 1 by reciting the limitation that the method further comprises one or more step of dissolving the isolated beta glucan in an aqueous solution, precipitating the beta glucan by adding between 10% to 20% (vol/vol) of the C_1-C_4 alcohol to the aqueous solution, and isolating the beta glucan. Claim 29 recites the method of claim 1 wherein about 15% to about 17% (vol/vol) of the C_1-C_4 alcohol is added to the purified extract in step (iii). Claim 16 recites a method of isolating beta glucan from a milled cereal grain or a milled part of the cereal grain, comprising: (i) extracting the milled cereal grain or milled part of a cereal grain with an alkaline solution having a pH of between 9 to 10 for a period of time of about 15 to about 45 minutes to produce an extract comprising at least about 0.4 weight % beta glucan; (ii) removing insoluble material and removing particulate material having a particle size of greater than about 0.2 microns from the extract to produce a purified extract, wherein the step of removing particulate material comprises one or more steps of adding a flocculant, a coagulant or both a flocculant and a coagulant to said extract to coagulate particulate material having a particle size of greater than about 0.2 microns, and removing the coagulated material from the extract, enzymatically digesting starch material in said extract, and filtering out material having a particle size of greater than about 0.2 microns from the extract to produce a purified extract; (iii) adding about 10% to about 25% (w/w) of a C_1-C_4 alcohol to the purified extract to precipitate the beta glucan; and (iv) isolating the beta glucan. Claim 28 recites the method of claim 4, wherein the flocculant is selected from the group consisting of polyacrylamide, a

quaternary acrylate salt and a natural flocculant macromolecule, and the coagulant is selected from the group consisting of alum, lime, ferric chloride, ferrous sulfate, an organic polymer and a synthetic polyelectrolyte with anionic or cationic functional groups. Claims 30 and 31 recite the method of claim 16 wherein about 10 to about 20% (vol/vol), specifically about 15% to about 17% (vol/vol), of the C_1-C_4 alcohol is added to the purified extract in step (iii).

25. Bhatty teaches a method for extracting beta glucan (including beta (1-3) beta (1-4) glucan; col. 2, lines 40-43) from milled cereal grain (including cultivars of barley, oat, wheat, rye, corn, sorghum and millet; col. 2, lines 37-39; col. 3, lines 12-21) comprising extraction with an alkaline solution with a pH from 8-14, particularly pH 10-12 (col. 3, lines 22-27), removing insoluble (particulate) material by centrifugation, dialysis or filtration (note that the particles of Bhatty would inherently be larger than 0.2 microns; col. 3, lines 46-48), adding about 20% to about 90% alcohol (including the C_1 to C_4 alcohols methanol, ethanol, propanol and butanol; col. 3, line 63-col. 4, line 5), and isolating the beta-glucan (col. 4, lines 5-8). The extract produced by the initial extraction with an alkaline solution of Bhatty would inherently contain from at least about 0.04 to about 1.3% beta glucan, because Bhatty discloses the use of cereals and milled cereal grains as starting materials which comprise from about 6.6 to 13.4% beta glucan, and that about 63-95% of the beta glucans are extractable, therefore the starting materials contained from about 4.2-12.7% extractable beta glucans (63% of 6.6% is about 4.2%, and 95% of 13.4% is about 12.7%; Tables II and IV); the cereal to solvent ratios used range from 1:10 to 1:100, therefore the alkaline extracts would contain about 0.04-1.3%

beta glucans (4.2% divided by 100 is about 0.04%, and 12.7% divided by 10 is about 1.3%; col. 3, lines 38-44); since the extract of Bhatty is produced by the methods claimed in the instant application, the extract produced by Bhatty would have inherently contained beta (1-3) beta (1-4) glucan within the claimed range. Bhatty teaches that the step of removing particulate material can comprise the addition of a flocculant and/or coagulant to coagulate particulate material, which would have a particle size of greater than 0.2 microns (an acid is used as the coagulant/flocculant; col. 3, lines 48-54), removal of particulate material from the extract by centrifugation (col. 3, lines 52-54), digestion of starch material in the extract using an enzyme (col. 3, lines 53-56) and filtering out of particulate material from the extract (col. 3, lines 63-65). Bhatty teaches that the pH of the alkaline solution can adjusted to about 7 (neutral) prior to enzymatic digestion (col. 3, lines 48-56). Bhatty teaches that step wherein the alcohol is added to the beta glucan extract can be conducted at 4 degrees C (Fig. 1, step 7). Bhatty teaches the further step of dissolving the beta glucan in an aqueous solution and precipitating again with alcohol and isolating the beta glucan by centrifugation (Fig. 1, step 9). The alkaline extraction step of Bhatty is generally carried out for between about 2 and about 25 hours (col. 3, lines 41-42).

26. Potter teaches a method for extraction of beta glucan wherein the alkaline extraction step is carried out for about 0.5 to about 3 hours (abstract, col. 5, lines 13-18).

27. As discussed above, it would have been obvious to combine the teachings of Bhatty and Potter to arrive at a method for the extraction of beta glucan comprising

nearly all of the claimed elements. Neither of the references, however, teaches the use of a flocculant and/or coagulant selected from the group recited in the claims.

28. Morgan teaches a method of the extraction of beta glucan wherein proteins are removed by adding a flocculant, such as carageenan, a natural flocculant molecule and an organic polymer (p. 5, lines 1-6).

29. A method for extraction of beta glucan comprising nearly all of the claimed elements was known in the art at the time of the invention, as discussed above. Further, it was known at the time of the invention that a flocculant, including the claimed flocculants, could be used to remove protein in a process for the extraction and purificastion of beta glucan, as taught by Morgan. One of ordinary skill in the art would have been motivated to combine these teachings because Potter discusses the need for forming a flocculant from proteins by heating or cooling for removal during purification of beta glucan (col. 5, lines 42-60). Morgan discusses an alternative method which comprises the addition of a flocculant. Thus, there existed in the prior art at the time of the invention a known alternative to the heating and cooling for removal of proteins taught by Potter, i.e. the use of a flocculant, as taught by Morgan. One of ordinary skill in the art would have recognized that the use of a flocculant could have been applied to the combined method of Bhatty and Potter to yield predictable results, i.e. the flocculation of proteins from the beta glucan solution, as taught by Morgan. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because Morgan teaches that the use of a flocculant is suitable in similar process for the purification of beta glucan. It would therefore have

been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed method.

Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

30. Applicant's arguments filed October 25, 2007 have been fully considered but they are not persuasive. Applicant argues that neither Bhatty nor Potter teach or disclose an extraction step with the specific combination of pH and time recited in the claims, and that Bhatty specifically teaches away from using basic solutions with shorter extraction periods. Applicant argues that neither Bhatty nor Potter teaches the use of the claimed amounts of alcohol in the alcohol precipitation steps, and that the references do not teach the use of the claimed flocculants and/or coagulants.

31. In response to applicant's argument that neither Bhatty nor Potter teach or disclose an extraction step with the specific combination of pH and time recited in the claims and that Bhatty specifically teaches away from using basic solutions with shorter extraction periods, applicant is directed to Bhatty at col. 3, lines 30-33, wherein the reference teaches that "if the beta-glucan extract will be further purified, rather than discarded, the pH of the base will be such that the beta-glucan molecule remains generally intact." Thus, Bhatty teaches the use of lower pH ranges in processes for further purification of beta-glucan. Potter teaches that the preferable pH for the process is 10 and that extraction times of 0.5 hours are suitable (col. 5, lines 5-18). The

motivation to combine these references is discussed above; further, at the time of the invention there existed a finite number of identified extraction methods for beta-glucan, the use of solution with pH 10 for 0.5 hours, as taught by Potter, being one of them. One of ordinary skill in the art could have pursued this known potential solution with a reasonable expectation of success because the method of Potter was known in the art at the time of the invention to have been a suitable method for the extraction of beta glucan. Thus, it would have been obvious to one of ordinary skill in the art to combine the methods of Potter and Bhatty to arrive at the claimed invention. Thus, applicant's assertion that the cited references fail to teach the claimed elements is not found persuasive.

32. In response to applicant's argument that neither Bhatty nor Potter teaches the use of the claimed amounts of alcohol in the alcohol precipitation steps, it is noted that, although applicant recites in some of the dependent claims the use of up to about 17% alcohol to precipitate the purified extract, Bhatty teaches the use of "about 20%" alcohol to precipitate the purified extract; even if it is found that "about 20%" alcohol does not anticipate applicant's recitation of "about 17%" alcohol, this amount have been arrived at by one of ordinary skill in the art in the course of routine experimentation, as evidenced by Bhatty's teaching that the amount of alcohol used to precipitate the purified extract can be varied (col. 4, lines 1-8). Applicant's argument is therefore not found to be persuasive.

33. In response to applicant's argument that the references do not teach the use of the claimed flocculants and/or coagulants, it is noted that this claimed element is taught

by Morgan. The teachings of Morgan have been discussed above, as has been the motivation to combine the cited teachings.

34. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is

(571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A Davis/
Primary Examiner, AU 1651